

## REMARKS

Interview request

Applicants respectfully request a telephonic interview after the Examiner has reviewed the instant response and amendment. Applicants request the Examiner call Applicants' representative at (858) 720-5133.

Status of the Claims*Pending claims*

Claims 1 to 4, 6 to 12, 14 to 17, 47, 48, 74 to 80, 84 to 86, 88, 89, 92, 102 to 108, 112 to 116 and 118 to 166 are pending. Claims 74, 108, 112 to 116 and 118 to 121 remain withdrawn. Accordingly, 1 to 4, 6 to 12, 14 to 17, 47, 48, 75 to 80, 84 to 86, 88, 89, 92, 102 to 107 and 122 to 166 are pending and under consideration.

*Claims added and canceled in the instant amendment*

In the present response, claims 7 to 9 are canceled, without prejudice or disclaimer, and claims 167 to 175, are added. Thus, after entry of the instant amendment, claims 1 to 4, 6, 10 to 12, 14 to 17, 47, 48, 75 to 80, 84 to 86, 88, 89, 92, 102 to 107 and 122 to 175 will be pending and under consideration.

*Restriction Requirement, Election and Rejoining process claims*

In response to the Restriction Requirement mailed May 22, 2003, Applicants elected Group 62, for the genus of nucleic acids having a sequence identity SEQ ID NO:125, vectors, host cells, probes and a method of making the encoded polypeptide (SEQ ID NO:126), with traverse and argument. As noted in their response of February 24, 2004, Applicants respectfully requested that, after the elected product claims have been found to be allowable, all withdrawn process (methods) claims which depend from or otherwise include all of the limitations of the allowed product claims be rejoined.

*Outstanding Rejections*

Claims 1 to 4, 6 to 12, 14 to 17, 48, 75 to 80, 84 to 86, 88, 89, 92, 102 to 107, 124 to 128 and 131 to 146 are rejected under 35 U.S.C. §112, second paragraph. Claims 10 to 12, 17, 75 to 80, 84

to 86, 88, 89, 92, 128, 129, 132, 133, and 136 to 142 are rejected under 35 U.S.C. §112, first paragraph, written description requirement. Claims 1, 6 to 12, 16, 17, 47, 48, 75 to 80, 84 to 86, 88, 89, 92, 122 to 130, 132, 133 and 136 to 142, are rejected under 35 U.S.C. §112, first paragraph, enablement requirement. Claims 75, 76, 84, 85 and 92 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Tachibana et al. (Database GenBank, US National Library of Medicine (Bethesda, MD, USA), No. D83793, TACHIBANA et al., 01 February 2000) (“Tachibana”). The rejection of claims 88 and 89 under 35 U.S.C. §103(a) as allegedly obvious over Tachibana in view of the state of the art has been maintained.

Applicants respectfully traverse all outstanding objections to the specification and rejection of the claims.

#### Support for Claim Amendments

Support for the new and amended claims can be found throughout the application for the skilled artisan. For example, support for claims directed to polypeptides of the invention lacking a signal sequence, or further comprising a heterologous sequence such as a heterologous signal sequence, can be found, inter alia, in paragraph [0060], page 13, of the specification; which corresponds to paragraph [0060] of U.S. Patent Application Publication serial no. 20030125534 (“the ‘534 publication”).

Accordingly, Applicants submit that no new matter is introduced by the present amendments.

#### Issues under 35 U.S.C. §112, second paragraph

Claims 1 to 4, 6 to 12, 14 to 17, 48, 75 to 80, 84 to 86, 88, 89, 92, 102 to 107, 124 to 128 and 131 to 146 are rejected under 35 U.S.C. §112, second paragraph, for reasons set forth in page 3, line 4, to page 7, line 3, of the OA. The instant amendment addresses these issues. For example:

Claims 1 to 3, 10 to 12 and 143 (see lines 9 to 17, page 3, of the OA) are amended to read on “completely complementary” sequences;

Claim 8 (see lines 18 to 21, page 3, of the OA) is canceled;

Claims 10 and 11 (see line 22, page 3, to line 9, page 4, of the OA) are amended, and now encompass, inter alia, nucleic acids comprising a sequence encoding a polypeptide having alpha

amylase activity consisting of a sequence having at least 98% sequence identity to 150 consecutive amino acid residues of the amino acid sequence of SEQ ID NO:126; and, in claim 11, nucleic acids comprising a sequence encoding a polypeptide having alpha amylase activity consisting of a sequence having at least 99% sequence identity to 100 consecutive amino acid residues of the amino acid sequence of SEQ ID NO:126. Support for nucleic acids of the invention encoding polypeptide of the invention of 150 or 100 residues in length can be found in, inter alia, paragraphs [0176], [0181] and [0203] of the '534 publication.

Claim 12 (see lines 10 to 17, page 4, of the OA) is amended, and now encompasses, inter alia, nucleic acids comprising a sequence encoding a polypeptide having alpha amylase activity consisting of a sequence having at least 90% sequence identity to about 300 consecutive residues of the nucleic acid sequence of SEQ ID NO:125. Support for nucleic acids of the invention encoding polypeptides of the invention of 300 base pair residues in length can be found in, inter alia, paragraphs [0176], [0181] and [0203] of the '534 publication.

Claim 75 (see lines 18 to 22, page 4, of the OA) is amended, and now encompasses, inter alia, nucleic acid probes for identifying or isolating an amylase-encoding gene, comprising an oligonucleotide, wherein the oligonucleotide consists of at least about 75 contiguous nucleotides of a sequence as set forth in claim 2. The Office is correct in noting that the probe can comprise elements in addition to the oligonucleotide, for example, see claim 89, wherein the probes can further comprise a detectable non-isotopic label, e.g., a fluorescent molecule, a chemiluminescent molecule, an enzyme, a cofactor, an enzyme substrate, or a hapten. However, the oligonucleotide only consists of at least about 75 contiguous nucleotides of a sequence as set forth in claim 2. The instant amendment clarifies this point.

Claim 124 (see lines 1 to 6, page 5, of the OA) is amended such that the nucleic acid sequence identity is determined by using a method comprising use of a BLASTN program algorithm with default parameters or the polypeptide sequence identity is determined by using a method comprising use of a BLAST P algorithm with default parameters.

Claims 125 to 127 (see lines 7 to 16, page 5, of the OA) are amended and appropriately clarified.

Claims 136 to 137 (see line 17, page 5, to line 4, page 6, of the OA) are amended and appropriately clarified.

Claims 1, 2 and 143 (see lines 5 to 10, page 6, of the OA) are amended and appropriately clarified.

Claim 128 (see line 11 to 16, page 6, to line 3, page 7, of the OA) is amended and appropriately clarified.

Issues under 35 U.S.C. §112, first paragraph

Written Description

*Subsequences*

The rejection of claims 10 to 12, 17, 75 to 80, 84 to 86, 88, 89, 92, 128, 129, 132, 133, and 136 to 142 under 35 U.S.C. §112, first paragraph, is maintained for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention, for reasons set forth in the OA from page 7, line 4, to page 8, line 2, of the OA. In brief, the Office expressed concerns that the specification does not expressly set forth any examples of the specifically claimed enzymatically active subsequence species (e.g., of 100 or 150 amino acid residues) of the exemplary protein species SEQ ID NO:126.

However, Applicants respectfully submit that a description of the exact subsequence size and function of a biological sequence based on an exemplary sequence is sufficient to satisfy section 112, because an adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. As stated in MPEP §2163 II.A.3.(a):

Possession may be shown in many ways. For example, possession may be shown by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. See, e.g., *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) (the written description "inquiry is a factual one and must be assessed on a case-by-case basis"); see also *Pfaff v. Wells Electronics, Inc.*, 55 U.S. at 66, 119 S.Ct. at 311, 48 USPQ2d at 1646.

MPEP §2163 II.A.3.(a), page 2100-171, 8<sup>th</sup> ed. Rev 5, Aug. 2006; see also MPEP §2163.02, page 2100-179. The exact subsequence size and function of a biological sequence based on an exemplary sequence are a description of sufficient, relevant, identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. The MPEP further clarifies this point:

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. *Enzo Biochem*, 323 F.3d at 964, 63 USPQ2d at 1613. For example, the presence of a restriction enzyme map of a gene may be relevant to a statement that the gene has been isolated. One skilled in the art may be able to determine whether the gene disclosed is the same as or different from a gene isolated by another by comparing the restriction enzyme maps. In contrast, evidence that the gene could be digested with a nuclease would not normally represent a relevant characteristic since any gene would be digested with a nuclease. Similarly, isolation of an mRNA and its expression to produce the protein of interest is strong evidence of possession of an mRNA for the protein. [emphasis added]

MPEP §2163 II.A.3.(a), page 2100-172, 8<sup>th</sup> ed. Rev 5, Aug. 2006. The description need not be in *ipsis verbis* (i.e., "in the same words") to be sufficient, see, e.g., MPEP §2163, page 2100-173; and MPEP §2163.02, page 2100-179, 8<sup>th</sup> ed. Rev 5, Aug. 2006.

#### *Functional limitations*

The rejection of claims 17, 75, 128 and 129 under 35 U.S.C. §112, first paragraph, is maintained for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention, for reasons on page 8, lines 3 to 18.

The Office remains concerned that while the claimed probes of the invention (claims 17, 75, 128 and 129) may identify sequences encoding amylases, under the enumerated stringent conditions they may also identify, or bind to, sequences that do not encode amylases. In other words, the Office is concerned that the claimed probes of the invention can give a false positive, or hybridize to sequences under the enumerated stringent conditions that do not encode an amylase.

Applicants' respectfully submit that it is sufficient that a linking functional limitation for members of a genus work for its intended purposes to satisfy the written description requirement – particularly when a composition is being used as a research tool (a probe to isolate or identify a

protein-encoding sequence). Indeed, all claimed probes of this invention can – and must be able to – identify (bind to) amylase-encoding sequences (under the enumerated stringent conditions). That these probes may also bind a sequence that does not encode an amylase does not negate the effectiveness of the linking functional limitation for the purpose of satisfying section 112's written description requirement.

#### Enablement

Claims 1, 6 to 12, 16, 17, 47, 48, 75 to 80, 84 to 86, 88, 89, 92, 122 to 130, 132, 133 and 136 to 142 are rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly does not reasonably provide enablement for the claimed invention, for reasons set forth in the OA from page 8, line 19, to page 10.

The Office acknowledges that the specification is enabling for a genus of nucleic acids encoding a polypeptide having a sequence as set forth in SEQ ID NO:126.

Applicants respectfully aver that the specification enabled the skilled artisan at the time of the invention to identify, and make and use, the claimed genera of amylase-encoding nucleic acids, for reasons set forth in, inter alia, their last response, which is incorporated herein. For example, Applicants have provided sufficient evidence and expert declaration to support this argument, as set forth in their previous responses, e.g., of April 05, 2005; August 20, 2004; and, February 24, 2004, which are expressly incorporated herein.

However, to address one of the Office's basic concerns – which is the scope of the claimed genus – Applicants have further narrowed the scope of the claimed genus of nucleic acids to those having at least 90% sequence identity to the exemplary sequence of the invention.

Accordingly, in light of the above remarks and the present claim amendments, Applicants respectfully submit that amended claims are fully enabled by and described in the specification to overcome the rejection based upon 35 U.S.C. §112, first paragraph.

Issues under 35 U.S.C. §102(b)

Claims 75, 76, 84, 85 and 92 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Tachibana et al. (Database GenBank, US National Library of Medicine (Bethesda, MD, USA), No. D83793, 01 February 2000) (please note: Tachibana was reference "AQ", not "AK" in the IDS of September 29, 2003).

The instant amendment addresses this issue. As noted above, Applicants have further narrowed the scope of the claimed genus of nucleic acids to those having at least 90% sequence identity to the exemplary sequence of the invention.

In light of the instant amendment, Tachibana does not teach all of the elements of the amended claims. Accordingly, because Tachibana is not a single reference teaching each and every element of the claimed invention, withdrawal of the rejection under section §102 is respectfully requested.

Issues under 35 U.S.C. §103(a)

The rejection of claims 88 and 89 under 35 U.S.C. §103(a) as allegedly obvious over Tachibana in view of the state of the art has been maintained.

As discussed above, the instant amendment removes Tachibana as a single reference teaching each and every element of the claimed invention. The state of the art at the time of the invention does not cure the defect in Tachibana to teach the claimed (amended) sequences. Accordingly, the rejection of claims 88 and 89 under 35 U.S.C. §103(a) as allegedly obvious over Tachibana in view of the state of the art can be withdrawn.

CONCLUSION

In view of the foregoing amendment and remarks, Applicants respectfully aver that the Examiner can properly withdraw the rejection of the pending claims under 35 U.S.C. §112, first paragraph. In view of the above, claims in this application after entry of the instant amendment are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 564462006100. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

As noted above, Applicants have requested a telephone conference with the undersigned representative to expedite prosecution of this application. After the Examiner has reviewed the instant response and amendment, please telephone the undersigned at (858) 720-5133.

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Respectfully submitted,

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